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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,268

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Mitsuo Sekine

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EXAMINER

CRANE, LAWRENCE E

ART UNIT

PAPER NUMBER

1623

NOTIFICATION DATE

DELIVERY MODE

07/23/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/590,268	Applicant(s) SEKINE ET AL.	
	Examiner Lawrence E. Crane	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 22, 2006 (preliminary amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/04/06</u> . | 6) <input type="checkbox"/> Other: _____ |

The Abstract of the Disclosure is objected to because it does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

Applicant is respectfully requested to amend the abstract because the chemical process being disclosed in the abstract is incompletely described, and therefore the abstract fails to completely describe the process whereby the linking of the compound of claim 1 occurs with the solid support.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The instant disclosure fails to include "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to include the requested information as the first paragraph of the disclosure.

No claims have been cancelled, claims **6, 8, 12, 14 and 15** have been amended, the disclosure has not been amended at page 1, and no new claims have been added as per the preliminary amendments filed August 22, 2006. One Information Disclosure Statement (1 IDS) filed December 4, 2006 has been received with all cited references and made of record.

Claims **1-16** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line **y**, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

35 U.S.C. §101 reads as follows:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”

Claims **15 and 15** are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. §101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App., 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

Applicant is respectfully requested to amend claims **15 and 16** by substitution of an alternative for the term “use,” wherein said substitute term is not a derivative or a conjugation of the verb – to use --.

Claims **1-16** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for a specific process for the derivatization of a “highly cross-linked polystyrene” (aka “HCP”) solid support by reaction of a functional group attached to said HCP possibly with a compound of claim **1** to create a solid support derivatized to serve as the starting point for nucleic acid synthesis, does not reasonably provide enablement for any other process wherein a solid support is derivatized for the indicated synthetic purpose by a compound of claim **1**. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of “undue experimentation” is appropriate are as follows:

A. The breadth of the claims is found to exceed the enabling embodiments because the claims are directed to any solid support derivatized by a compound of claim **1** and the subsequent application of said derivatized solid support as a starting material in a phosphoramidite-type oligonucleotide synthesis process.

B. The nature of the invention: This subject matter was described in the previous paragraph.

C. The state of the prior art: A present there is no prior art of record that anticipates or renders obvious the instant claimed subject matter.

D. The level of one of ordinary skill: One of ordinary skill would be expected to be knowledgeable concerning organic synthesis and the synthesis of derivatized solid support with utility in the synthesis of oligonucleotides.

E. The level of predictability in the art: In view of the confused and incomplete nature of the subject matter as presently of record in the instant claims, it is presently not possible to determine the predictability for the entire scope of the subject matter, particularly when referring to the compounds of indeterminate structure referred to in claim 1 and some claims dependent therefrom

F. The amount of direction provided by the inventor: The instant disclosure provide less than 14 pages most of which is devoted to the description of how to make synthetic precursors. The disclosure at pages 17-19 only includes one operational set of embodiments to enable the claimed synthesis-capable solid support and its application to the syntheses of an oligoadenylate and an oligothymidylate. .

G. The existence of working examples: This subject matter was described in the previous paragraph.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is found to be excessive because of the indefiniteness and ill defined metes and bounds of the claims as presently in the case, and because of what appears to be a scope of claimed subject matter that is not adequately enabled by the very small number of specific embodiments.

Claims **1-16** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim **1** at line 3 is incomplete because the line formula provided fails to completely describe the genus of chemical compounds being claimed. This problem is not solved in any subsequent claim, including claims **10 and 11** wherein the chemical names provided appear to be equivocal; i.e. appear to be directed to more than one chemical structure.

In claims **4 and 5**, reference to “phosphate protecting group” is technically erroneous because claim 1 appears to describe phosphoramidites (P(III)), not phosphate esters (P(V)).

Claim **8** asserts that “a benzene ring structure has a substituent,” and thereby fails to further limit the scope of the claim depended from. Examiner suggests that claims **8 and 9** may be referring to an --additional substituent --.

Claim **12** is directed to a complex chemical structure only a few structural elements of which have been described thereby rendering the claim incomplete. Claims **13 and 14** add some details but not enough detail to overcome the problem with claim **12** even if incorporated within claim **12**.

Claims **15 and 16** are incomplete because both claims either independently or taken together fail to fully describe the process step of steps being claimed, let alone the chemical starting materials and reagents necessary to carry out the claimed process of oligonucleotide synthesis.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
07/19/2009

/Lawrence E. Crane/

Examiner, Art Unit 1623

L. E. Crane
Patent Examiner
Technology Center 1600